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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/658,824 | 09/08/2000 | Tongtong Wang | 210121.478C11 | 2868 |

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| EXAMINER | |
|---|---|
| MYERS, CARLA J | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1634 | |

DATE MAILED: 12/17/2002

12

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/658,824 | WANG ET AL. | |
| | Examiner | Art Unit | |
| | Carla Myers | 1634 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *02 October 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-23* is/are pending in the application.

4a) Of the above claim(s) *1-5 and 7-17* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *6 and 18-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *5, 7, 8* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

1. Applicant's election of group IV and SEQ ID NO: 808 with respect to claim 6 and newly added claims 18-23 in Paper No.10 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

2. The specification is objected to because page 1 of the specification does not provide the serial number for the application filed August 29, 2000. Additionally, the first line of the specification should be amended to clarify the relationship between the present application and PCT/US00/18061. The specification states that the present application is "related to" PCT/US00/18061, but does not indicate whether the present application is a continuation or a continuation-in-part of PCT/US00/18601.

3. Claims 6 and 18-23 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The following factors have been considered in formulating this rejection (*In re Wands,* 858F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988): the breadth of the claims, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, the amount of direction or guidance presented, the presence or absence of working examples of the invention and the quantity of experimentation necessary.

Claims 6 and 18-23 are drawn to methods for detecting the presence of cancer wherein said methods comprise contacting a sample with an agent that binds to a peptide comprising at least 10 or 20 amino acids of a polypeptide encoded by SEQ ID NO: 808 or a sequence having 75% identity thereto, detecting any peptide that binds to said agent, comparing the amount of polypeptide to a predetermined cut-off value and therefrom determining the presence of cancer in a patient. The specification teaches a cDNA for a clone "L552S" wherein the cDNA has the sequence of SEQ ID NO: 808. The specification also teaches a polypeptide encoded by said cDNA wherein said polypeptide has the sequence of SEQ ID NO: 809. In particular, the specification (pages 159-160) teaches that the cDNA of SEQ ID NO: 808 was isolated from a lung adenocarcinoma cDNA library and subtracted against a pool of normal human cDNA libraries of lung, liver, pancreas, skin, kidney, brain and resting PBMC. However, the specification does not provide any information on the level of expression of the polypeptide encoded by SEQ ID NO: 808 in lung cancer cells versus normal cells. Accordingly, the specification has not established that an increase in the quantity of the polypeptide encoded by SEQ ID NO: 808 is associated with the occurrence of human lung adenocarcinomas or any other type of cancer. The ability to diagnose cancer is highly unpredictable and the fact that a cDNA is detected in a cancer cell does not indicate that increased levels of expression of that cDNA will be associated with cancer. Additionally, the specification has not established that any protein containing 10 or 20 amino acids of SEQ ID NO: 809 will be correlated with the occurrence of cancer. No information is provided on any subfragments of the polypeptide encoded by SEQ ID

NO: 808 which are unique to cancer cells and would be expected to be present in other proteins that are associated with the occurrence of cancer. No guidance is provided in the specification as to which subfragments of the protein encoded by SEQ ID NO: 808 would be expected to be present in other proteins and which would be useful for diagnosing cancer. It would require undue experimentation to practice the claimed invention because this would necessitate screening the human genome and the genomes of other organisms for the presence of nucleic acids encoding 10 mer fragments of the polypeptide encoded by SEQ ID NO: 808, isolating the larger length or full length molecules, and assaying such molecules to determine whether they encode for proteins which are specifically expressed in cancer cells and not expressed in normal cells. The specification does not provide any information regarding the length, structure or functional activity of the larger or full-length polynucleotide or the peptide encoded thereby. Additionally, the claims include detecting polypeptides having 75% identity with the polypeptide encoded by SEQ ID NO: 808. However, the specification has not taught any variants of the polypeptide encoded by SEQ ID NO: 808 which would be associated with cancer. No guidance has been provided as to how to modify SEQ ID NO: 808 at specific positions so as to generate additional nucleic acids encoding for proteins that are correlated with cancer. It is highly unpredictable as to how modification of the polypeptide encoded by the polynucleotide of SEQ ID NO: 808 would alter the functional activity of the polypeptide and would affect its association with the occurrence of cancer. Additionally, the specification has shown only that the cDNA of SEQ ID NO: 808 is expressed in human lung adenocarcinomas. The specification has not

established that this cDNA is expressed in other types of cancer or in cancers from non-humans. Even if applicants were able to establish that the polypeptide encoded by SEQ ID NO: 808 is expressed at higher levels in human lung adenocarcinoma cells versus normal cells, such a showing would not lead one to a method for diagnosing any type of cancer. Lastly, the specification (page 65) teaches that "lung tumor proteins" are expressed at a level of at least a 2 fold increase in tumor cells versus normal cells. However, the specification does not define what constitutes a "predetermined cut-off value" and it is unclear as to what quantity of a polypeptide of SEQ ID NO: 809 or 10 mer or 20 subfragments thereof would be required to be indicative of cancer. Case law has established that "(I)t is the specification, not the knowledge of one skilled in the art that must supply the novel aspects of the invention in order to constitute adequate enablement" (*Genetech Inc. v Novo Nordisk* 42 USPQ2d 1001). In the instant case, the specification has not fulfilled this requirement because the specification has not adequately taught one of skill in the art how to detect the presence of cancer in a patient by detecting a polypeptide encoded by SEQ ID NO: 808, by detecting a polypeptide by a polynucleotide having 75% with SEQ ID NO: 808 or by detecting a polypeptide comprising any 10 or 20 mer fragment of a polypeptide encoded by a polynucleotide having the sequence of SEQ ID NO: 808 or sequence having 75% identity thereto.

4. Claims 6 and 18-23 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one

skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 6 and 18-23 are drawn to methods for detecting the presence of cancer wherein said methods comprise contacting a sample with an agent that binds to a peptide comprising at least 10 or 20 amino acids of a polypeptide encoded by SEQ ID NO: 808 or a sequence having 75% identity thereto, detecting any peptide that binds to said agent, comparing the amount of polypeptide to a predetermined cut-off value and therefrom determining the presence of cancer in a patient. While isolated polypeptides consisting of SEQ ID NO: 809 and isolated polypeptides encoded by SEQ ID NO: 808 meet the written description requirements of 35 U.S.C. 112, first paragraph, the specification does not disclose and fully characterize the claimed genus of any polypeptide **comprising** any 10 or 20 mer fragment of a polypeptide encoded by SEQ ID NO: 808 or any polypeptide encoded by a polynucleotide having 75% identity with a polynucleotide of SEQ ID NO: 808 . *Vas-Cath Inc. V. Mahurkar*, 19 USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed". Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. 112 is severable from its enablement provision. In *The Regents of the University of California v. Eli Lilly* (43 USPQ2d 1398-1412), the court held that a generic statement which defines a genus of nucleic acids by only their functional activity does not provide an adequate written description of the genus. The

court indicated that while Applicants are not required to disclose every species encompassed by a genus, the description of a genus is achieved by the recitation of a representative number of DNA molecules, usually defined by a nucleotide sequence, falling within the scope of the claimed genus. At section B(1), the court states that "An adequate written description of a DNA...'requires a precise definition, such as by structure, formula, chemical name, or physical properties', not a mere wish or plan for obtaining the claimed chemical invention". Accordingly, knowledge of the sequence of the 10 mer fragment encoded by SEQ ID NO: 808 does not allow the skilled artisan to envision all of the contemplated larger and full-length polypeptides encompassed by the claims. The claims require detecting proteins that have been defined with respect to only 10 amino acid residues. The specification does not sufficiently describe these proteins in terms of their structural properties (length, identity of flanking amino acid sequences, etc) or functional properties (e.g., activity of the encoded peptide). The specification does not teaches only the polypeptide of SEQ ID NO: 809 and does not teach any other polypeptides comprising 10 mer fragments of SEQ ID NO: 809. Additionally, the claims include detecting allelic variants of the polypeptide encoded by SEQ ID NO: 808. However, the specification does not adequately describe the structural and functional properties of any polypeptide encoded by a polynucleotide having 75% identity with SEQ ID NO: 808. Accordingly, Applicants have not provided sufficient evidence that they were in possession, at the time of filing, of the polypeptides required to practice the invention as it is broadly claimed and thus the written description requirement has not been satisfied for the claims as they are broadly written.

Applicants attention is drawn to the Guidelines for the Examination of Patent Applications under 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

5. Claims 8 and 18-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 8 and 18-23 are indefinite over the recitation of "predetermined cut-off value." The specification does not provide a clear definition for what is intended to be encompassed by this phrase and there is no art recognized definition for this phrase. Accordingly, one cannot determine what is intended to be encompassed by a predetermined cut-off value.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carla Myers whose telephone number is (703) 308-2199. The examiner can normally be reached on Monday-Thursday from 6:30 AM-5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached on (703)-308-1152. The fax number for the Technology Center is (703)-305-3014 or (703)-305-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the receptionist whose telephone number is (703) 308-0196.

Carla Myers

December 12, 2002

Carla Myers
CARLA J. MYERS
PRIMARY EXAMINER